K110778

510K Summary

JUL 29 2011

Owner's name: Biodenta Swiss AG

Address: Tramstrasse 16
9442 Berneck
Switzerland
Phone: +41 71 747 11 11
Fax Number: +41 71 747 11 12

Contact Person: Mr. David Eiler, Regulatory Manager

Date Summary prepared: July 29, 2011

Trade name: Biodenta Customized Abutment
Common Name: Endosseous dental implant abutment
Device classification name: abutment, implant, dental, endosseous

Product Code: NHA
Regulation number: 21 CFR 872.3630

Legally marketed device to which equivalence is claimed (predicate device):

Company: Pou Yu Biotechnology Co., Ltd.
Device Name: TDS Abutment for Nobel Biocare Replace
510(k) number: K091026

Company: Pou Yu Biotechnology Co., Ltd.
Device Name: TDS Titanium Abutment for Nobel Branemark
510(k) number: K091392

Company: Friadent GmbH
Device Name: XiVE TG Abutments
510(k) number: K032302

Company: Lifecore Biomedical Inc.
Device Name: PrimaConnex CAD/CAM Abutment System
510(k) number: K072241

Company: Atlantis Components, Inc.
Device Name: AtlantisTM Abutments in Zirconia for 3i Certain Interface
510(k) number: K063734

Indications for Use:

The Biodenta Customized Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

The Biodenta Customized Abutment is compatible with the following implant systems:

-Internal hex systems with flat-to-flat dimensions of 1.78mm or greater: Friadent: FRIALIT Implant, XiVA Implant, 3i:Certain Internal Connect Type; Astra: Osseospeed Implant, Osseospeed TX implant; Biohorizons: Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System; Lifecore: Lifecore RENOVA Internal Hex Implant System; Zimmer: Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System.
-Nobel Biocare Replace: NobelReplace Straight, NobelReplace Tapered; Replace Select Tapered, Replace Select Straight; for the NP, RP, WP and 6.0 implants.
-External hex systems with flat-to-flat dimensions of 2.4mm or greater: Nobel Biocare Branemark, 3i, BioHorizons, and Lifecore.

Device Description:

Biodenta Customized Abutments are titanium abutments designed to be used in conjunction with specific dental implants utilizing the Biodenta customized abutment screws to secure the abutment to the implant. In combination with the implant, the abutments support single or multi-unit cement-retained restorations in the maxillary and/or mandibular arch.

The abutment is milled using computer-assisted technology that enables the creation of final abutments that are manufactured with specific geometry. The abutment is made from titanium grade Ti-6AL-4V ELI (meets ASTM standard F-136). The abutment screw and interface is made from titanium grade Ti-6AL-4V ELI (meets ASTM standard F-136).

The Biodenta Customized Abutment is compatible with the following implant systems:

-Internal hex systems with flat-to-flat dimensions of 1.78mm or greater: Friadent: FRIALIT Implant, XiVA Implant, 3i:Certain Internal Connect Type; Astra: Osseospeed Implant, Osseospeed TX implant; Biohorizons: Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System; Lifecore: Lifecore RENOVA

Internal Hex Implant System; Zimmer: Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System.
-Nobel Biocare Replace: NobelReplace Straight, NobelReplace Tapered; Replace Select Tapered, Replace Select Straight; for the NP, RP, WP and 6.0 implants.
-External hex systems with flat-to-flat dimensions of 2.4mm or greater: Nobel Biocare Branemark, 3i, BioHorizons, and Lifecore.

Non-clinical Testing Data:

Fatigue testing was conducted according to ISO 14801 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants with the worst case scenario for each Biodenta Customized Abutment connection platform. These results show that Biodenta Customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the implant systems for which they are intended.

Equivalence to marketed device:

Biodenta Swiss AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Biodenta Customized Abutment is substantially equivalent to the predicate devices in intended use, material composition (except to K072241 and K063734 which are zirconia), fundamental scientific technology, principles of operation, and basic design. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for Biodenta Customized Abutment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biodenta Swiss AG
C/O Ms. Angela Blackwell
Senior Consultant
Biologics Consulting Group
Tramstrasse 16
Berneck
Switzerland 9442

JUL 29 2011

Re: K110778
Trade/Device Name: Biodenta Customized Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 19, 2011
Received: July 20, 2011

Dear Ms. Blackwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

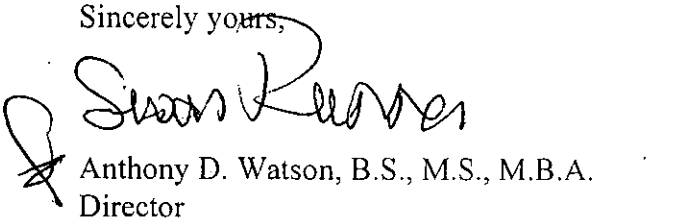
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

biodenta®

Indications for Use

510(k) Number (if known): K110778

Device Name: Biodenta Customized Abutment

Indications for Use:

The Biodenta Customized Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

The Biodenta Customized Abutment is compatible with the following implant systems:
- **Internal hex systems** with flat-to-flat dimensions of 1.78mm or greater: Firadent: FRIALIT Implant, XiVA Implant; 3i: Certain Internal Connect Type; Astra: Osseospeed Implant, Osseospeed TX Implant; BioHorizons: Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System; Lifecore: Lifecore RENOVA™ Internal Hex Implant System; Zimmer: Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System.
- **Nobel Biocare Replace:** NobelReplace Straight, NobelReplace Tapered; Replace Select Tapered, Replace Select Straight; for the NP, RP, WP and 6.0 implants.
- **External hex systems** with flat-to-flat dimensions of 2.4mm or greater: Nobel Biocare Branemark, 3i, BioHorizons, and Lifecore.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110778